

Digital Health Ecosystems for Sensor Technology Integration - A Qualitative Study on the Paradox of Data Openness

Completed Research Paper

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Abstract

Mobile health startups develop innovative, sensor-based solutions that continuously collect health data. To generate added value from these large amounts of data, an integration of the solutions into the healthcare system is essential. In this context, the collaboration between interdependent healthcare stakeholders is required which can be enabled by structures considered as digital ecosystems. To understand the conditions for ecosystem participation, more specifically the incentives and disincentives for data openness, we conducted 30 interviews with four healthcare stakeholder groups in Germany and analyzed the data using a Grounded Theory approach. As a result, we developed a conceptual model that describes the integration of mobile sensor-based health solutions into digital health ecosystems. Thereby, we improve the understanding of incentives and disincentives for data openness on the collective ecosystem level, the ecosystem-stakeholder-group level, and the individual user level. Practically, we contribute by outlining important market entry barriers for mobile health startups.

Keywords: Digital health ecosystem, data openness, mobile sensor-based health technology

Introduction

The past years have seen a rise in innovative technologies, primarily driven by mobile health startups introducing monitoring or diagnostic applications enabled by smart algorithms and mobile sensors. Sensor-based solutions allow to continuously acquire “big data” (Raghupathi and Raghupathi 2014), help create high-definition risk profiles (Torkamani et al. 2017), support patient engagement (Chiauzzi et al. 2015), allow more accurate interpretation of disease symptoms (Raij et al. 2011), and facilitate self-tracking (Gimpel et al. 2013). In this way, care services become more preventive, cost effective, and precise. However, “big data” created by sensor-based tracking and tracing is also met with resistance (e.g. in the case of the Covid-19 tracking application) for reasons often related to unwanted surveillance of one’s private behaviors (Raij et al. 2011) as well as unilateral value claims by private companies (Zuboff 2019). Therefore,

the incentives to collect and share health data openly are pronounced differently and depend on the stakeholders' perspective. Policies in favor of a user's privacy protection, allowing for a choice of with whom their health data is shared, run counter to the companies' preference towards (more exclusive) access to "big" health data and to developing more innovative offerings (Nambisan et al. 2019). This "paradox of openness" (Arora et al. 2016) describes the tension between the creation and appropriation of value and illustrates that focusing on the openness of health data on one level, for instance on the individual user level, ecosystem-stakeholder-group level or collective ecosystem level exclusively, is not feasible. This calls for a more nuanced, stakeholder-differentiated view on sensor-based health technologies.

The purpose of this paper is to *conceptualize incentives and disincentives, as well as barriers for data openness and sharing, in the context of integrating sensor-based health technologies into digital health ecosystems*. Sensor-based solutions allow for a stronger interconnection of different actors and enable, but also require structures that are commonly discussed under the term "ecosystem." An *ecosystem* can be defined as a "set of actors with varying degrees of multi-lateral, non-generic complementarities that are not fully hierarchically controlled" (Jacobides et al. 2018). While some researchers have highlighted that these ecosystems often emerge in the context of digital platforms through which the ecosystem participants become connected (Parker et al. 2017; Song et al. 2018) others have described more dispersed forms of coordination in innovation ecosystems (Adner 2017; Giudici et al. 2018; Jacobides et al. 2018). In the healthcare field, ecosystem-based coordination via digital means is only in a nascent stage in many European countries, as illustrated by the Digital Health Index published by the Bertelsmann Stiftung (2018). In considering digital health readiness, actual data use, and policy activity, the tailights of the countries studied are formed by Switzerland, France, Germany and Poland which are ranked lowest (in descending order). To enable service provision for patient value, defined as the betterment of the patient's condition (Rantala and Karjaluo 2016), the interdependencies of healthcare stakeholders need to be considered. There is a (non-digital) ecosystem that in many countries such as Germany (our country of focus), centers around three stakeholder groups: patients, medical service providers, and health insurance companies. The patients pay a monthly fee according to the insurance contract with their health insurance and are treated by medical service providers in a case that they may fall sick. Medical service providers are reimbursed by the health insurance according to their contracts and depending on the provided treatment (Busse et al. 2006, p. 2). All interactions between these stakeholders are strictly regulated and subsidized, as is the use of medical devices (Busse et al. 2006, p. 18).

Within Europe, and particularly in Germany, the development of provider-specific solutions and the lack of a national digital health infrastructure creates a heterogeneous technological landscape. This causes conflicts when the cooperation between different solutions or the consumption of services by other providers is needed (Benedict and Schlieter 2015). It further aggravates the fragmentation of the market by creating proprietary data formats and silo solutions. From a theoretical perspective, this absence of prospering digital ecosystems calls for research into the rules and roles, and monetization, as well as how actors are connected, which have been identified as important requirements for ecosystem formation (Jacobides et al. 2018). In particular, we posit that technology-oriented streams of research on health ecosystems (Benedict and Schlieter 2015; Vesselkov et al. 2019) should be extended by considering the ecosystem concept also in a socio-economic and strategic light, as well as considering how sensor-based *hardware* (Olla and Shimskey 2015), in contrast to software-based solutions, is integrated into digital ecosystems and which specific challenges arise. In parallel, country-specific characteristics and their associated legal and regulatory requirements play an important role, e.g. particularly in Iceland (Islind et al. 2019) or Finland (Vesselkov et al. 2019) where similar studies with a slightly different focus have been conducted. Furthermore, new measures at the national and European levels are currently being announced over short intervals, such as with the European health cloud Gaia-X (The Economist 2020). This, in contrast, creates high degrees of uncertainty for startups who want to enter the market. Since business models cannot be pre-planned safely, incentives exist to collect "big data", despite consequences on the individual level, as this could maximize the chances of a company's survival. This may alleviate the tension between those positive effects enabled by sharing sensor-generated health data openly and the concerns by different stakeholders on different levels to do so.

To address these issues as well as their implications, we conducted 30 interviews with stakeholders in the emerging mobile sensor-based health technology (MSHT) ecosystem in Germany. This ecosystem includes the actors, activities, and those relationships involved in providing sensor-based solutions for use with patients in order to create added value for them. Interviews were coded using the Grounded Theory

approach, and within that process we viewed the collected material through three purposeful lenses: (1) *incentives and disincentives of ecosystem participation from a multi-stakeholder perspective* (Jacobides et al. 2018), (2) ecosystem participants' stances toward *openness and control* (Nambisan et al. 2019), and (3) the *principles of the data economy* (Zuboff 2019). From the systematic coding of the interviews and our subsequent theory building effort, we have derived a conceptual model on the integration of sensor-based health solutions in a digital health ecosystem. Furthermore, we identified that design and governance strategy, in light of the *paradox of openness*, consist of two main phases within which different forms of restrictions and controls apply. In this regard, we have identified different incentives and disincentives for data openness and data sharing which are dependent on the stakeholder group and/or ecosystem level.

We contribute a phase- and stakeholder-differentiated consideration of the incentive differences in the strategic design of healthcare ecosystems, as requested by Nambisan et al. (2019). Mobile health startups, health insurances, and medical service providers have very different incentives for data openness and data sharing which play out on different levels; namely, the collective ecosystem level, the ecosystem-stakeholder-group level, and the individual user level, all of which we will argue should be considered in future research. From a practical viewpoint, we inform MSHT integration in the context of digital health ecosystems by identifying stakeholder-specific barriers to market entry, which can be addressed through various framing, nudging, and regulatory strategies.

Theoretical Foundation

The concepts of *mobile sensor-based health technology* (MSHT) and *digital ecosystems* are described in the following to define the scope of our study and to show their relation to the existing literature. We then go on to develop our own perspective, synthesizing important insights from digital ecosystems, data openness and the role of data in the context of health service improvements and business model development.

Mobile Sensor-based Health Technology

On one side, medical and research grade sensor devices generally promise a high accuracy and are often targeted at unhealthy or elderly patients and are designed for the management of a certain disease e.g. diabetes (Gao et al. 2015). But these devices can be expensive, their outer appearance can be bulky and it is hard for the user to set up the device independently. In stark contrast, the term fitness tracker is constantly evolving and is generally defined as wearable technology that is worn on the wrist (Swan 2012), which is more accessible to the average consumer and often mentioned in contexts in the fitness sector to help healthy, young users track their daily lifestyle data (Gao et al. 2015). The convergence of the usability of fitness trackers and the accuracy of medical sensor devices is demonstrated by various attempts of mobile health startups to enter the healthcare market with medically certified end user products and services. In this context we conceptualize the term **mobile sensor-based health technology** (MSHT). The word “mobile” implies that the sensor is flexible and wearable so that it can be worn on the user’s body continuously. The device can be used independently without the support of medical professionals and is targeted at the end-consumer (e.g. patient). The word “sensor” represents the integration of any type of sensor technology with the goal of capturing vital parameters of its user e.g. inertial measurement units (linear and angular motion) or galvanic skin response sensors (skin conductivity). The exact sensor position on the user’s body varies, as does its shape e.g. as wristbands or headbands. The concept of “health technology” defines that sensor technology is applied in a medical and health related context.

Digital Ecosystem

In the context of digital ecosystems there are different research paradigms. Deriving from the platform evolution framework of Tiwana et al. (2010), Schreieck et al. (2016) went on to frame key concepts and issues for future research in connection with the design and governance of platform ecosystems. In contrast to Tiwana (2010), they broadened the rather technical definition of platform “architecture” and morphed it into “design”, which includes a conceptual blueprint of the ecosystem as a whole (Schreieck et al. 2016). Within their findings, they reveal the issues with an “individual level of analysis to consider characteristics of actors” as well as “the role of data as boundary resource” (Schreieck et al. 2016). Hein et al. (2019) describe different foci on digital platform ecosystems within the existing literature e.g. technical, social,

economics or business paradigms only. In contrast to this single-paradigm research they introduce a nuanced approach that integrates “the intra-organizational technical perspective on digital platforms and the inter-organizational economic, business and social perspectives on ecosystems” (Hein et al. 2019). Such an approach is close to our own understanding of ecosystems. In the context of our research question (see Introduction), we consider technical aspects of MSHT, social aspects of stakeholder characteristics and collaboration incentives, as well as business aspects of economic efficiency and subsidization of treatment costs within the healthcare system to be of great importance. For this reason, we differ from existing contributions that focus on single paradigms and instead follow this new approach to digital platform ecosystems.

The conceptual work of Adner (2017), Kapoor (2018) and Jacobides (2018) extends platform-centric views by broader and more conceptual definitions of the ecosystem construct. Adner (2017) views ecosystems as a combination of “ecosystems as a structure” and “ecosystem as an affiliation” approach. So a digital health ecosystem encompasses several healthcare actors that perform interdependent activities. According to Kapoor (2018) “an ecosystem encompasses a set of actors that contribute to the focal offer’s user value proposition”, which refers to the collaboration of several healthcare stakeholders to create patient value. Like in biological ecosystems (with the term *ecosystem* originating from (Moore 1993)) there is an evolution over time that influences the ecosystem’s members in regards to their collaboration, innovation and competition. This somewhat mirrors the historical development of a healthcare system which then still heavily influences the way it is working today. The product or service offer can be designed with (or even without) a technological architecture that is based on a platform (Kapoor 2018); in this context, the digital health ecosystem can also be designed in a decentralized way. Jacobides (2018) focuses on the types of complementarities and resulting mechanisms and defines ecosystems as “a set of actors with varying degrees of multi-lateral, non-generic complementarities that are not fully hierarchically controlled” (Jacobides et al. 2018).

While these previous contributions have highlighted important aspects of ecosystems from a platform-centric and multi-lateral coordination point of view, there has been limited attention paid to the context in which these ecosystems do and do not emerge. One important context condition for the integration of MSHT is the **high regulation on the healthcare market** that is, for instance, caused by medical device certification guidelines and data security standards. Secondly, there are **social policy objectives** (e.g. high quality of care) that meet **economic policy objectives** (e.g. promotion of entrepreneurial activity) that are often contradictory (Saltman et al. 2002). These contradictions and context conditions create an interesting opportunity to study the (non-)formation of ecosystems in situ and to understand the factors that hinder or promote the creation (and simultaneous non-creation) of ties between ecosystem actors.

For developing our own perspective on ecosystem design and governance strategy, Jacobides et al. (2018) provide a detailed description of different governance and regulation mechanisms. Digital ecosystem success and the behavior in it are influenced by the **rules of engagement**, as well as the nature of interfaces and standards which include open-versus-closed and imposed-versus-emergent ecosystems. Standards within an ecosystem can either be proprietary or sector-wide and are defined either (a) de facto, especially if they are not based on technology or (b) de jure, especially if there are many ecosystem members. For each, there is a certain degree of ecosystem membership control e.g. by a central hub. The rules for membership within the ecosystem may vary over time which also relates to the modularity and nature of complementarities within an ecosystem.

Governance is closely related to **decision-right allocations** (who is responsible for ‘what’) as well as the enforcement of desirable behavior, which in this context can be called control. This is complicated by the absence of the authority structure of a central actor (Jacobides et al. 2018). Extending upon the notion of Jacobides et al. (2018) and borrowing from Tiwana et al. (2010), we refer to **control** in an ecosystem context as *the formal and informal mechanisms implemented by an ecosystem firm to encourage desirable behaviors among other ecosystem participants*. Formal mechanisms can relate to output or process control, controlling what other firms produce (or use) and which processes they must follow (Tiwana et al. 2010). Informal control refers to social pressure, as well as the development of shared norms and values which are imposed on or emerge from ecosystem members. One of the most important governance mechanisms are boundary resources (Schrieck et al. 2016) which consider technological as well as social aspects of platform ecosystems (Eaton et al. 2015). Data that is provided by platform users and can be accessed by complementors (Gawer 2014) is a boundary resource that is gaining importance in

practice. This is especially relevant in the MSHT context where huge amounts of health data are collected that need to be made accessible to complementors and interoperable within all ecosystem members to facilitate (co-)creation of value.

Closely related to the governance of an ecosystem is its **openness**. While openness has been discussed in different domains regarding different objects (Arora et al. 2016; Baldwin and Hippel 2011; Lessig 2001), it has also been picked up by Jacobides et al. (2018) in their agenda for future research on ecosystems. We focus on data openness as one important concept that is subject to different views and opinions. In line with Lessig (2001), we define data as open *if its use is “free,” meaning that one can use it without permission from anyone else or if the permission one needs is granted neutrally*. This does not mean that openness implies sharing without costs, but it implies non-discriminatory access to data, such as when it is governed by pre-defined neutral licenses. Managing such data sharing requires making design and governance decisions that maintain the tradeoff between promoting generativity to facilitate complementors’ contributions and retaining control to prevent undesirable platform use (Vesselkov et al. 2019). Generativity can be defined in this context as the ability to spark unbounded growth, facilitated by large, uncoordinated audiences (Zittrain 2008, p. 70). The seeming tension that arises between benefits from open data sharing on the one hand, and conflicting interests to do so on the other hand, has been called the “paradox of openness” (Arora et al. 2016), and recent research has called for new perspectives on this paradox in the healthcare context, which our contribution sets out to do using the context of MSHT and its integration into emerging digital health ecosystems.

Any description of these governance mechanisms would be incomplete without mentioning the technological preconditions enabling the emergence of ecosystems as well as their evolution in the first place. Jacobides et al. (2018) note that one important prerequisite is modularity, the decomposition of a system into smaller components that one can “mix-and-match” relatively easily (Schilling 2000). As Zuboff (2019) insightfully notes, modularity is a circle of *behavioral data* created from “users,” **analytics**, and **service improvements**, enabling the creation of *surplus* from *rendered behavior*. This, in turn, can be used to create new data-driven business models balancing the tension of openness and control, thus designing specific distributions of value claims, which are more “unilateral” (favoring the one-sided monetization of prediction-based insights by private firms) or more “bi- or multi-lateral” (favoring the distribution according to universally accepted and agreed societal standards). What is interesting in the MSHT ecosystem is that stakeholders can take the role of **data producer** and of **consumer**, so that they become data prosumers (Vesselkov et al. 2019). Similarly, the monetization of data and developing prediction-based business models is clearly limited, making this an interesting study context. The main tenants of our perspective form a stakeholder-differentiated view on incentives and disincentives for data production, sharing, and usage, as well as a simultaneously social, technical and economic view on ecosystem emergence and evolution. Highlighting this, figure 1 synthesizes the different views into our own perspective on MSHT integration into the healthcare ecosystem, which the remainder of this paper sets out to explore and deepen.

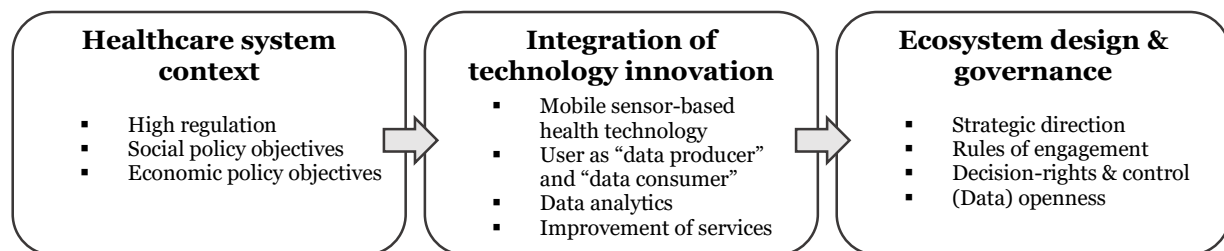


Figure 1. Core Constructs to Be Explored and Deepened in Research Study

Methodology

In the following we explain the methodological approach of our qualitative interview study. The motivation for this paper is to investigate the phenomenon of mobile sensor-based health technology integration from four different stakeholder perspectives within the context of digital health ecosystems (Myers and Avison 2002). The benefit of a qualitative research approach is that the cultural and social context in which decisions take place can be apprehended well (Benbasat et al. 1987). In the “natural context” of the

healthcare system this is particularly relevant because personal experiences and legal requirements often highly influence stakeholders' decisions (Myers 2019). The best way to understand stakeholders' actions and motivations as well as the context in which they take place is by talking with people (Myers 2019, p. 5). For this reason, we chose expert interviews that are semi-structured and guideline based to enable an in depth-review. The phenomenon under study is relatively new, such that across (and even within) stakeholder groups it is likely that different terminologies and phrases are emerging. For this reason, the underlying philosophical assumption of our research is interpretive (Klein and Myers 1999) since we need to interpret these meanings to be able to grasp the respective phenomenon.

While designing the semi-structured interview guideline for **data collection**, three aspects were given special attention (Baur and Blasius 2014, p. 567): to avoid sudden changes in topic in order to establish a narrative flow, to give the interviewee enough time to speak by providing a clear structure and a limited number of questions and to encourage the interviewee to narrate freely. During the preparation of the interview guideline we followed the four steps that were introduced by Cornelia Helfferich (2011) which resulted in 15 questions. These are grouped under six headings (Introduction, MSHT characteristics, Health data integration, Technology integration, Process integration and Future development) to enhance the structure of the interview. There was a pre-test of the interview guideline to assure a clear wording and an overall common thread. For every stakeholder group, the detailed interview guideline was adapted slightly to match the related role or field (e.g. company/hospital). At the beginning of the interview there was a brief introduction of the researcher as well as the research project to clearly state the purpose of the interview (Myers 2019, p. 133). The concept of "mirroring" was applied during the conversation (Myers and Newman 2007). This means that phrases and words employed by the interviewee are subsequently used by the interviewer to phrase their following questions or comments. At the end, there was the opportunity to ask further questions and then the interviewee would be thanked for their provided insights (Myers 2019, p. 133). All interviews were conducted in the German language by one researcher.



Figure 2. Stakeholder Map

The initial **case selection** is inspired by the European Connected Health Alliance Ecosystem (European Connected Health Alliance 2019) that identifies several stakeholder groups within its ecosystem (see figure 2). In total four stakeholder groups have been included within our study because they represent the phenomenon of MSHT integration (Corbin and Strauss 1990) and have a high accessibility. The first (1) stakeholder group included are companies which are represented by mobile health startups (MHS). Startups are conceptualized as "young, growth-oriented firms that engage in innovative behavior" whose growth rate can be higher than that of mature companies (DeSantola and Gulati 2017). Mobile sensor-based health technologies are innovative products/services and there are no prominent large corporations, but rather small businesses operating in the healthcare sector targeting the end user. These businesses try to enter the market with a new digital technology they try to integrate into the existing healthcare system. The second (2) stakeholder group is represented by statutory health insurances (SHI) because they pay the service providers for the treatment of patients while respecting the legal guidelines for reimbursement. The medical service providers (MSP) are the third (3) stakeholder group that is included in our review. This comprises general physicians, medical care centers and hospitals which have to choose the information technology that is included in medical service provision (and at the same time act as a "business" which compares costs and revenues). As a fourth (4) stakeholder group we also decided to include institutes & incubators (I&I). They act as supporting stakeholders within the healthcare system and advise, consult and conduct research within healthcare. Therefore, they provide a holistic view of the overall healthcare system. To enable a triangulation of subjects (Rubin and Rubin 2005, p. 67) and counteract elite bias (Miles and Huberman 1994; Myers 2019) we aim to include a variety of experts on different hierarchical levels within each stakeholder group that represent a variety of perspectives. In general, only stakeholders that are active in the German healthcare market are considered to ensure the comparability of the legal framework.

Overall, experts were defined as persons that are either German or English speaking employees, have at least one year of working experience (or in the case of very young companies, that have been working there from the beginning) and either have a technical or a medical background. Potential interviewees were contacted directly via mail or LinkedIn (# interview requests = 89). A brief description of the research project and its overall objectives was attached in the initial message to make sure the interviewee felt confident enough to answer the interview questions. The interviews (n=30) took place between October 2019 and April 2020 and were either conducted in person (1/30), via video conference software (2/30) or via telephone (27/30). An overview of the interviewed stakeholders is depicted in figure 3. The interviewees have an average experience of 7,2 years within their field. This comprises the shortest experience of 9 months and the longest experience of 40 years within the medical domain. After the interviewees gave their informed consent (Payne and Payne 2004, p. 68), all interviews were recorded using the Philips DVT2710 dictating machine. The average interview duration was 46 minutes, which includes the shortest interview of 32 minutes and the longest interview with a duration of 72 minutes. To enable the qualitative analysis of data each audio file was transcribed.

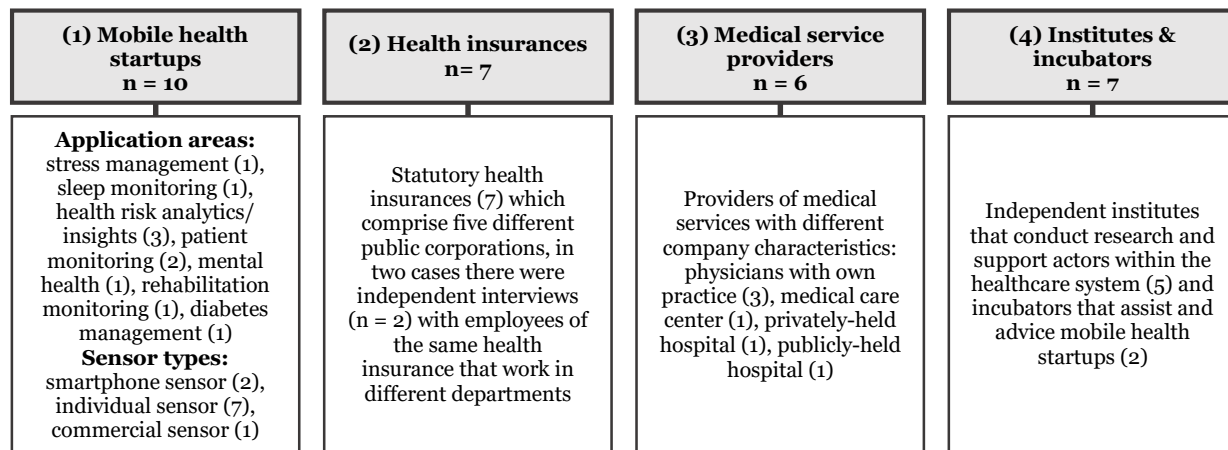


Figure 3. Interviewee Numbers and Affiliations

The **data analysis** of interview transcriptions started parallel with the collection of further interview data. We paid special attention to the representativeness of concepts in the choice of interview partners (Corbin and Strauss 1990). To allow for an inductive development of theory that is based on empirical data, we chose the Grounded Theory approach (Martin and Turner 1986). Grounded Theory is frequently used in information systems research “to study technological change and social technical behavior in emerging research domains” (Wiesche et al. 2017). This resonates with our objective to study the integration of constantly evolving innovation (MSHT) into a digital healthcare ecosystem that depends on the collaboration and acceptance of various stakeholders. Additionally, Grounded Theory offers a high degree of flexibility (Birks et al. 2013) and there are various methodological approaches within the existing literature. We chose the Straussian approach because it provides a frame for students that prefer to work with a preset structure (Mey and Mruck 2010) as well as an “unambiguous process guidance” (Wiesche et al. 2017, p. 689). The paradigm for coding should be consistent with the research question (Mey and Mruck 2010) as well as with the researchers position (Birks et al. 2013). Initially, we consider the a priori chosen coding paradigm of the Straussian approach (Corbin and Strauss 1990), which are *conditions*, *context*, *strategies* and *consequences* to fit our data well (Birks et al. 2013). The coding of data is performed according to the three steps proposed by Strauss & Corbin (1990). To support the process of qualitative data analysis Atlas.ti (v.8 for Windows) software was used as well as memos to keep track of our hypotheses and questions throughout the coding process. In the first step of open coding, a sentence-by-sentence analysis was performed by assigning concepts to the text fragments of the interview transcripts and continuously comparing them with one another (Corbin and Strauss 1990). In order to illustrate the process of open coding, the text “[...] but the entire mobile data systems with the platform behind them and medical applications, they must be reimbursable for companies like us, otherwise we will be dependent on investors for a long time to come. Germany in this area is financed by investors and German investors are not so willing to take risks anyway.” was coded as follows: *reimbursement conditions*, *access to financing*, *risk tolerance*. After open coding (# total codes = 239), the codes were checked for duplicates and (especially

those with rare occurrence) reviewed (# total codes = 204). If possible, this also includes merging semantically similar codes e.g. *hacking* and *information security* (# total codes = 181). Next, to form categories and sub-categories, conceptually similar codes were grouped (# total concepts = 107) e.g. *human intervention* and *replacement of humans* both describe the concept of the *level of human involvement*. In the second step of axial coding, relationships that are grounded in the data are assigned between categories and their subcategories. This is done by following the coding paradigm of *conditions*, *context*, *strategies (action/interaction)* and *consequences* (Corbin and Strauss 1990). We deviated slightly from the original paradigms within the coding process because we felt that the theory development would be enhanced by renaming some of the categories (Mey and Mruck 2010). We therefore merged *context* and *conditions* to *context conditions* (because within the phenomenon under study the conditions arise from the context) and customized *consequences* to *outcomes*. In the final step of selective coding, all identified categories are unified around a core category (*integration of mobile sensor-based health technology*), which has the most relationships to the remaining categories and represents the central phenomenon of the study (Corbin and Strauss 1990).

Integration of Mobile Sensor-based Health Technology into a Digital Health Ecosystem

We turn to the results of our analysis regarding the integration of mobile sensor-based health technology into digital health ecosystems. Table 1 displays 107 concepts and their number of appearances in brackets (# appearances) as a result of all three coding steps. Additionally, their assignment to the 18 sub-categories (right table column in *italics*) and the four main categories (**bold** table captions) that are included in the final conceptual model are displayed. Direct quotes from the interviews are presented in quotation marks and the stakeholder group of the interviewee is indicated in brackets. The over-arching categories that emerged were *context conditions*, the *integration of mobile sensor-based health technology*, *digital health ecosystem design and governance strategy*, and *outcomes*. The following sections detail these findings and point to apparent tensions and contradictions.

We define the first category **context conditions** as the overall factors and requirements for the integration of MSHT into the healthcare system. *Society's mindset* describes the overall attitude of the public for instance if they are willing to track personal health data. The *healthcare system* illustrates special characteristics within the (German) healthcare system e.g. the *status quo* of the system “[...] more in the sense of a preventive system and not in the sense of a repair system. And that we get away from this shallow medicine that we are making now” (MSP), if there are specific *reimbursement conditions* and *system evolution* over time, for instance “Then I always try to explain to them that these [traditional measurement devices] were not created because one was clever at the time, but because it developed historically.” (MSP). *System agility* describes the speed and flexibility of actions, e.g. “and [in other countries] it makes me feel like things are getting back to the hospital bed faster, into use. In Germany there is still a lot of bureaucracy and forms.” (MSP). *Data regulation* includes *data protection* of the user against privacy impairments through e.g. unauthorized data access and *information security* which refers to the characteristics of technical and non-technical systems that store and process information. In this context, the right of the user to *data deletion* might collide with medical *data archiving* obligations. *Quality requirements* represent the need for medical certification if sensor devices are used for a medical purpose. Depending on the *certification procedure* and *certification classes*, the effort can be very high regarding costs and time. Next to this, the benefit of the application needs to be proven: “so you really have to have determined the benefit of this application in care [...]” (I&I).

Integration of mobile sensor-based health technology illustrates the core phenomenon of the conceptual model. The *user* of the technology includes everybody that is affected by its integration e.g. patients, physicians, caregivers, etc. Every user has a *self-image* and some intrinsic motivation to use the technology which can also depend on *technology affinity*. The *application* of the *technology* is location independent and “the usability must of course be designed for this use case, e.g. the app and also the devices themselves must be built so that they work as intuitively as possible.” (MHS). The sensor device is low-threshold and can be easily integrated in the user’s everyday life e.g. “But how can I make it so easy for the user that s/he has no additional effort at all and therefore just uses it?” (I&I). The *technology* that is used includes a *mobile sensor* and is therefore able to monitor user data continuously, often in combination with an app or smartphone. Depending on the maturity of the sensor technology, the devices have a certain

degree of *error-proneness*. Each sensor device provides some kind of *data acquisition*, for instance “we record movement data 24 hours a day” (MHS) with a specified *data accuracy*. *Data diversity* describes the collection of many different types of data e.g. “when certain patterns come together in patients, which can also be sensor data, but also laboratory data, diagnosis constellations, etc., then it becomes interesting.” (MSP). After health data is captured it needs to “flow” between different stakeholder groups to enable their collaboration. This *data flow* includes the import of data into a stakeholder’s systems or devices, for instance “The physician in turn, when s/he receives the measurement results, can import them into his/her practice EDP system [...]” (MHS). The imported data must be stored so e.g. “We store 99% of the data on the server, which is then retrieved by the app on a regular basis, but a few things are stored locally, of course, to make it fast.” (MHS) is a possible solution for *data retention*. If data from different sources is imported, the consolidation of this data is necessary, for instance “[...] if I can really import, merge, perhaps with other data from the medical field, then I can of course do much, much more exciting analysis.” (SHI). There is also the possibility for *data export* that is often provided by generating pdf- or csv-files. For import as well as export of data, *data transmission* is essential as well e.g. “so the sensor on the arm joint is connected to the smartphone app via Bluetooth. And the app is then connected to our servers via mobile phone network.” (MHS). In contrast to that *data sharing* is independent of the technological basis but rather focuses on the stakeholders that are involved, for instance “[...] transferred to a server to ensure access for doctors, relatives, patients etc.” (MHS). Within *data processing*, there is medically relevant and valid health data that facilitates *data analysis* e.g. “and there [on our servers] the calculation runs with our models, which we are currently training, also with Machine Learning.” (MHS). Depending on the *amount of data* there are different means of data analysis e.g. “So I’m a friend of big data pools and I’m also a friend of big data analytics and deep learning systems.” (MHS). After *data processing*, which describes the types and means of analysis, *data interpretation* (which can also be incorrect) describes the derivation of instructions for actions, user feedback, etc. Large data amounts also enable *predictions* within the healthcare system, for instance “And especially in the area of predictions, this is very, very meaningful data [...]” (SHI). Another important feature is *data visualization* e.g. “The added value is created by making the activity profile visible, through the companion app [...]” (MHS) and the way it is implemented: “A graph that goes from very fit very slowly to increasingly sick, that’s what makes a difference.” (MHS).

Digital health ecosystem design and governance strategy describes (inter)actions of the stakeholder groups that influence each other as well as the entire ecosystem. *Policy control* describes *legal guidelines* within the ecosystem. To define guidelines, the necessary knowledge and experience within the respective area are essential (which may still need to be acquired). Someone needs to be responsible for *compliance control* of these guidelines, but also to define them in the first place, e.g. “until the legal framework for [...] is established and how concretely the whole thing is defined. It is difficult to combine all sorts of things without a clear definition.” (I&I). Every stakeholder can interpret the guidelines in a different way, with one interviewee saying, “Now comes the joke: but the interface is interpreted a little differently by each company, so it’s actually not a standard. You always have to tinker with it a bit.” (MHS). If there is a *system transition* within healthcare from an analog to a digital ecosystem, then this process needs to be managed carefully. *Data openness* describes the interoperability of data within the system which requires semantic, as well as syntactic standards, that enable the “flow” of the data between stakeholder groups. If a stakeholder possesses the *data sovereignty*, s/he has the right to decide who can e.g. access it. Also, application programming interfaces (APIs) can enable the interoperability of systems even if there are different data formats. If the data format of a sensor is not compatible with other applications, there can be a *lock-in*. All data that is captured needs to be collected at a certain point which is recognized by every stakeholder (e.g. electronic medical records). We learned from one interviewee that “[...] what possibilities arise from these patient files to really be able to integrate such data and make it available to users is enormous.” (SHI). *Community engagement* describes the commitment of the stakeholders within the ecosystem and what incentivizes them to participate. For the stakeholders to collaborate there needs to be *trust* amongst each other e.g. “We cannot afford to be dependent on interfaces that some manufacturer supplies and possibly delivers uncertainly [...]” (MHS) or *trust* in the technology, for instance “We trust that this data is accurate enough.” (MHS). To accept new technologies e.g. sensor devices, stakeholders must be open to change, “[...] you have to open yourself again internally and say ok, do you really still need it?” (MSP). Every stakeholder has a defined role within the system that can change over time. Additionally, an *introduction and explication of innovation* is necessary e.g. “[...] and forget to bring in the person who will somehow prescribe, use or explain it to the users every day.” (SHI). Within the system, stakeholders can assume responsibility e.g. for a certain role. “But if s/he makes it available to the health insurance and

receives a reimbursement, e.g. s/he gets money from the community or something is paid, then I think I can give data back to the community.” (I&I) describes the (necessary) *community spirit* or the feeling of belonging within the ecosystem. To be able to succeed within an ecosystem and process transactions, stakeholders need to be able to orientate themselves and navigate through the ecosystem. The *product-market strategy* describes the *product/service design* of stakeholders within the ecosystem. *Monetization* illustrates if and how stakeholders receive a certain amount of money, as explained by one interviewee “[...] it must also be economically viable, it must be accountable, the cash flows must be mapped.” (MHS). The *access to customers* describes how product/service offers reach potential customers, which also depends on the *target group*. The *market access* represents how stakeholders enter the healthcare market. In this context *access to financing* is also particularly important for mobile health startups, “because you are normally always externally funded and have to invest some development time to bring the product to market.” (MHS). To cooperate with other stakeholders, the alignment of their strategies is of importance so “that we have entered into cooperation with startups and that we have said that what they have, the app or whatever, fits in with our focus [...].” (SHI). The business models within the fitness and lifestyle market differ from those in a medical context.

Context conditions	
Public perception (26), Self-tracking need (3), Willingness to optimize (2)	<i>Society’s mindset</i>
Reimbursement conditions (63), System agility (36), Status quo (23), Country-specific differences (17), Public law (15), System evolution (12), Self-organization (5), Solidarity principle (5)	<i>Healthcare system</i>
Data protection (60), Information security (41), Data deletion (28), Data archiving (12)	<i>Data regulation</i>
Proof of benefit (34), Certification classes (22), Certification procedure (21), Certification effort (20), Quality label (7)	<i>Quality certification</i>
Integration of mobile sensor-based health technology	
Self-image (35), Usage motivation (31), Health & data literacy (18), Technology affinity (11)	<i>User</i>
Simplicity in use (43), Use case specific (39), Location independence (31), Low-threshold application (18)	<i>Application usability</i>
Mobile sensor (100), Error-proneness (20), Technological maturity (3)	<i>Technology</i>
Type of data collection (110), Data accuracy (60), Continuous monitoring (29), Data diversity (17)	<i>Data acquisition</i>
Data retention (57), Data sharing (38), Data transmission (37), Data export (20), Data consolidation (13), Data import (10)	<i>Data flow</i>
Data analysis (34), Data validity (20), Amount of data (16)	<i>Data processing</i>
Data visualization (44), Data interpretation (43), Prediction (22), Data based decision (16)	<i>Data interpretation</i>
Digital health ecosystem design and governance strategy	
Legal guidelines (63), Compliance control (26), Definition of requirements (24), Assignment of responsibility (15), Necessary knowledge/experience (14), Design sovereignty (7), Interpretation of requirements (5), System transition (4)	<i>Policy control</i>
Data sovereignty (87), Semantic & syntactic interoperability standards (80), Data collection point (51), (Open source) APIs (45), Lock-in (9), Data harmonization (3)	<i>Data openness</i>
Stakeholder (participation) incentives (43), Trust (41), Stakeholder collaboration (28), Stakeholder acceptance (26), Openness to change (21), Role definition (19), Assumption of responsibility (17), New actors (17), Introduction & explication of innovation (13), Community spirit (6), Orientation within the system (6)	<i>Community engagement</i>
Product/service design (46), Access to customers (42), Monetization (41), Access to financing (25), Market power (19), Boundary between fitness and medical devices (18), Target group (16), Market access (16), Strategic alignment (15)	<i>Product-market strategy</i>

Outcomes	
Transparency (33), Ethics (24), Protection against misuse (21), Modernization/digitization level of the system (19), Research for common good (17), Decision rules (13), Nature of participation (10), Risk tolerance (10), Paradigm shift (8), Sustainability (4), Level of agreement (3)	<i>Shared value system</i>
Process modification (67), Level of human involvement (52), Changes in time expenditure (48), Changes in cost expenditure (37), Stakeholder burden (25), Complexity (15)	<i>System efficiency</i>
Quality change in care (70), Prevention (42), User empowerment (33), Behaviour change (24), Quality of life (17), Personalized medicine (10), Value-based care (10)	<i>Healthcare quality</i>

Table 1. Results of Grounded Theory Coding Process

Outcomes represent possible consequences that the (non-)implementation of the strategies can cause at different levels of the (digital) health ecosystem. *Shared system values* describe a common understanding of values within the entire ecosystem, which includes a certain *level of agreement* from (all) stakeholders in regards to specific topics. It also describes how risks and uncertainties are handled within the ecosystem. There needs to be a *protection against misuse*, to which all stakeholders adhere to and prevent that “[...] the data is simply used in a discriminatory manner against the user.” (SHI). Additionally, *decision rules* that are clear to everybody have to be implemented, especially if the opportunities outweigh the risks of a new technology. *Transparency* within the ecosystem can facilitate a *paradigm shift* that fundamentally changes the status quo. Big data algorithms and pattern recognition can be used to conduct *research for the common good*, for instance “You gain new knowledge about clinical pictures and the course of the disease. By comparing with other, perhaps anonymized, data.” (SHI). The nature of stakeholder participation in the ecosystem can either be on a voluntary or obligatory basis. *System efficiency* illustrates the modification of the existing processes within healthcare which can cause *changes in time and changes in cost expenditure*. Also the *level of human involvement* can be modified within medical service provision e.g. “And with us in the program, it’s not a physician right now, it’s our virtual coach [...]” (MHS). The *stakeholder burden* is influenced and either results in relief or overstrain, which can also be connected to high *complexity*, for instance “So I see this lack of clarity and this flooding and overburdening of health applications [...]” (MHS). Further, the *healthcare quality* (of service provision) for the patient can change, which would then include the definition of “quality” or “value” within *value based care*. Large amounts of continuously collected health data enable *personalized medicine* and might lead to a *behavior change* of the user, for instance “I measure it, I make myself aware of it and that’s why I change my lifestyle.” (SHI). *User empowerment* enables a focus on *prevention* – “We are very much in the prevention area and it is about enabling patients or insured persons to better manage themselves from the outset.” (SHI), which finally impacts the *quality of life*.

Discussion

We turn to discussing how we can conceptualize incentives and disincentives as well as barriers to data openness and sharing. This becomes relevant when integrating MSHT into digital health ecosystems. Figure 4 shows our conceptual model and illustrates the relations between the four main categories and 18 sub-categories. Relations between main categories are depicted by bold grey arrows and relations between sub-categories are represented by small black arrows. The four main categories are *context conditions*, the core phenomenon in form of a *health service improvement cycle*, *digital health ecosystem design and governance strategy* and *outcomes*.

Barriers to Entry

Before a mobile health startup enters the ecosystem, we identified that it faces obliging to strict guidelines (formal controls) and other contextual prerequisites. The perception of society is influenced by *data regulation* especially connected to the *healthcare system*, for instance, that data leaks have a deterrent effect on the overall trust in MSHT. Moreover, *quality certification* which describes medical device certification guidelines, is influenced by *data regulation* (because respective requirements are included in the guidelines but are also applied in other contexts) as well as by the context of the *healthcare system*. For instance, in the fitness and lifestyle sector it is not mandatory. Medical device regulation is necessary if the device/software is used for a medical purpose: “The approval as a medical device is the prerequisite for me

to be allowed to market it at all.” (MSH). If they are certified it is still complicated to enter the healthcare ecosystem “which has been a very, really closed shop so far, and is very narrowly limited.” (SHI). Up until now the conditions for reimbursement are defined in selective contracts with SHI according to the insurances’ requirements. In the future, the reimbursement of MHS products/services in Germany will be controlled by a recently introduced law (Digitale Versorgung Gesetz) which also includes strict guidelines, as well as cost and duration efforts. We learned from one interviewee that “[...] these certification processes take so much time that even good solutions are bled dry financially before they hit the streets.” (I&I). These are the legal guidelines that were only recently passed, but the MHS business models highly depend on these changes. For this reason, they have to be flexible and agile to adapt to changing conditions in the future. Within the quality certification, the MHS disclose their algorithms, data accuracy and service design so the “proof of benefit” can be evaluated by medical device certification authorities. For example, “[...] software products for digital work, server portals, mobile apps etc., algorithms must be certified as medical devices [...] as a manufacturer you have to guarantee that digital data – which can have a therapeutic effect – must be a medical device [...]” (MHS). This elaborate process creates high entry barriers for the ecosystem.

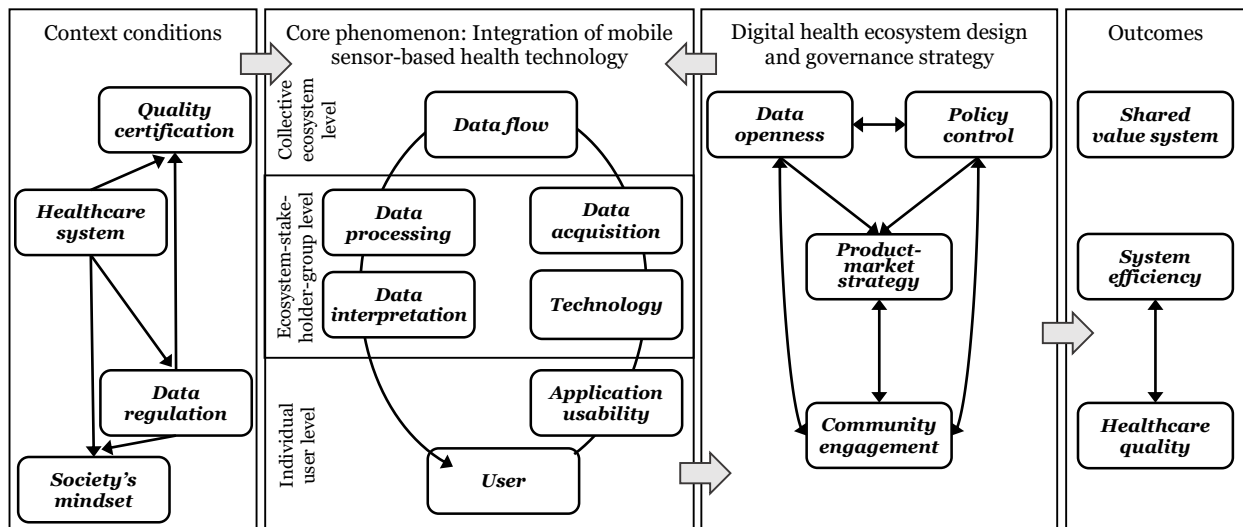


Figure 4. Conceptual Model of MSHT Integration

Health Service Improvement Cycle and the Challenge of Data Openness

Once a mobile health startup enters the market, we find the core phenomenon to be depicted by the data cycle that is enabled by MSHT. The user (data producer) applies sensor technology that captures diverse health data in a continuous way, such as one’s heart rate. The easier the technology is to use, the more often the user will employ it and a higher wear time results in the collection of a larger amount of (continuous) health data. For advanced calculations, in most cases the data is transmitted to a (central) storage and analysis location. Within this data collection point, there is a consolidation with other health data. To offer added value for the user, an interpretation of their health data is necessary (through the data consumer, for instance MHS) which is simultaneously seen as improving the service offer e.g. “your ECG data indicate atrial fibrillation”. To communicate the results, a clear and graphical presentation of (aggregated) health data is essential, which is often depicted on an (external and larger) screen. With the amount of accessible health data, the possibilities for algorithmic and interpretative improvements increase, while the likelihood for error is reduced. This allows for an additional product/service improvement for the user which will result in a higher adoption rate and in turn to more availability of users’ health data. Also, MSP can be data producers, for instance, by adding captured patient health data to the central data collection point. MSP can also be data consumers, for instance, by looking at independently collected patient data for treatment improvement. Additionally, SHI can take the role of a data consumer to improve their service for insured persons e.g. offering individual recommendations. While the technology supported acquisition of data, as well as its processing and interpretation, are carried out by one stakeholder group, the flow of the data and its consolidation is happening on a collective ecosystem level. The more data producers participate, the larger the “data treasure” becomes that can be used to facilitate service improvements. There are still strict

policies regarding data protection, but in the context of health data standards, whose interoperability is essential to generate digital health innovation, there is no clear definition of a uniform standard (formal control), nor of an informal control through data standard agreements between (all) ecosystem members. For this reason, low data standard (formal and informal) control causes low data openness. In this stage, MHS are active on the healthcare market and (partly) reimbursed by healthcare insurances. There is, for one, “the issue of interoperability [...] Standards are a very big topic, which plays a role here.” (SHI). At the moment there is no uniform data standard to adhere to. It is opined that, “If only you could agree on such a standard and everyone would adhere to it really seriously. In this respect, we always create something new for everyone.” (MHS). Even if two stakeholders use the same standard or interface, there are often differences between them due to the interpretation of guidelines and the consequent creation of individual solutions e.g. “Theoretically, yes, but practically, there is nothing. Everyone has an individual solution and everyone has the problem [...] and then everybody builds an own standard on the standard.” (MHS). As a consequence, we find that there is low data openness within the healthcare ecosystem. The missing definition of a data standard and compliance control causes interoperability issues, in that “[...] if I have any standard, then I can work with it, then I can transfer it to other standards, so that is much more important than anything else. It must be standardized. It must be a format that works across everything.” (I&I).

In this context, “the business model is important to us, that the digital health service is not designed to exploit or sell the data.” (SHI). The predominant type of monetization for MHS is to be reimbursed by (statutory) health insurances, for instance “B2C, which is difficult in Germany because we have a low self-payer willingness, and B2B2C, e.g. about the refund [...]” (I&I). In related fields where companies collect large amounts of data through products/services for which there is no direct willingness to pay (like MHS do), there are often business models enabled by a surplus of behavioral data (Zuboff 2019). Within healthcare it is strictly forbidden to use data for other purposes than those they were originally collected for. For this reason, MHS cannot receive compensation from third parties for their selling of data. If they would do so, this would likely be accompanied by a loss in trust, e.g. “to make people feel, yes it is a solidarity system, that is why you get the therapy, but that is why you are not part of any bigger business models that you do not know anything about or where you cannot defend yourself against.” (I&I). This illustrates the difficult process for MHS to develop sustainable business models within the German healthcare system.

This is also a challenge in terms of service improvement through big data analysis. While the demand for high control of ecosystem access is reasonable (e.g. for MHS) in the sensitive context of the healthcare system, the low data openness within this ecosystem tends to be caused by an absence of control, even though there are also calls for action. This is highlighted in rationals such as, “[...] ok all other countries do it, we just have to agree on it and participate. It is not as if it were somehow impossible to define it and to make progress on it.” (I&I). While one challenge in the context of a uniform data standard within healthcare is its definition, there are also different needs regarding data openness within the system or the “paradox of openness”. It illustrates that incentives for openness of data differ depending on stakeholder and ecosystem level (Nambisan et al. 2019). To reveal potential conflicts across levels, we chose to explain the incentives for high and low openness on three different levels. The *collective ecosystem level* describes the overall environment of the digital health ecosystem encompassing all members. Within the *ecosystem-stakeholder-group level*, for instance, activities that are performed by one stakeholder group, such as data interpretation by MSP, are described. The *individual user level* includes categories that change depending on individual users who can be members of the same stakeholder group e.g. different patients prefer different MSHT usability characteristics.

Collective Ecosystem Level. With the motivation to conduct research for the common good e.g. to enhance the understanding of disease symptoms, there need to be large amounts of health data, so “one acquires new knowledge about disease patterns or progression. By comparing with other, perhaps anonymous data, for example, how are others dealing with these diseases [...]” (SHI). This enables an earlier intervention for other patients, so “that, if you go back to the beginning of the disease, this data can help others who may be showing symptoms.” (I&I). In order to compare and analyze such data, we must use the same data standard. As one interviewee aptly stated, “Of course, if I want to compare data now, I need to have them in the same format in the best case, so that I can run an AI over them [...]” (SHI). If there is more data, then there is also the possibility for different compensation models, such that, “If you look at compensation, for example, we always had the discussion, wouldn't it need quality-based compensation? Where you said that is totally difficult, because you would need good data for quality-

oriented compensation. You haven't had that before and you may have it with the digital health applications in the future because you have completely different data availability, for example.” (SHI). In this context there is the concept of value-based care where existing incentive systems can be modified so that the patient benefits from high quality care. Still, a standard for “value” within care needs to be defined, which may be even more difficult than the definition of a data standard. Thus, overall, there are mainly benefits in the context of high data openness on the collective ecosystem level.

Ecosystem-Stakeholder-Group Level. Within the three stakeholder groups that are actively involved in data openness (I&I are excluded), the incentives differ. *Mobile health startups'* product/service offerings have to be applied by medical professionals in a simple and intuitive way, otherwise there is no wide adoption. As one interviewee suggested “[...] we can connect with other applications, let's say create a certain standard of interfaces [...] to adapt these processes in care in such a way that it does not mean more work for the carers, but actually makes things easier.” (MHS). Overall, if all data were to be compatible, the sensor devices might become a generic complement (Jacobides et al. 2018) within the ecosystem and the added value would be created by an app (for example) that analyzes the data which can be imported from any source. In this case, there is more competition between MHS that offer services for similar disease patterns e.g. diabetes management. If every application can import the data, a company has to differentiate itself from other companies. Currently, SHI have the power to decide which product/service is reimbursed, which is one of the only business models for MHS within healthcare at the moment. For MHS, data openness creates another approach to monetization and sustainability, as well as value-based business models, “so there would just have to be a business model where you can earn money, for example, by organizing care better, more efficiently, etc., by providing better individual, data-supported care than with collective care.” (SHI). It would appear that MHS are also interested in data openness, as long as their data is not used by competitors.

At the moment, *statutory health insurances* are not allowed to access or own any health data of the user e.g. collected by MHS. Even though public opinion varies and users are afraid that SHI possess health data via one's usage of an app that is reimbursed. We were told that “most [patients] think we already have data [...]. That is actually the perception of most of the insured with whom we speak [...]. However, we have nothing.” (SHI). If SHI possess continuous sensor data from a user, s/he might be worried that insurance fees are adapted according to the “healthiness” of behavior. At the moment, SHI have a relatively passive role and act as payer within the system. In the future however, they wish to change their role to an (active) healthcare partner or (neutral) healthcare navigator transitioning “the topic of health insurance away from the pure cost carrier and we are only the payer in the system, but we want to become a player, so become a health service provider, a navigator.” (SHI). This would also include an improvement of the communication with insured persons and improve the service experience (cf. MHS) e.g. “how to approach them with such a digital service and how to pitch it to them.” (SHI). At the moment, SHI are the player, where the data of all different MSP comes together. Still, service improvements are not possible with the data that is provided today nor with the overall speed of the system. Instead, “today we have accounting data, routine data. That's nice that we have them, but they are very limited, both in quality and in terms of having them on time. [...] In other words, if we think about active supply management now, they will only help us to a very, very limited extent.” (SHI). It would seem that for SHI to be interested in data openness, they must be able to offer predictions e.g. regarding health risks for insured persons (if they wish to receive any).

Within the group of *medical service providers*, the interest in openness varies widely depending on single stakeholders “because there are many practices that are, as I said, a bit older or have existed for a longer time and are perhaps not as open to new things. Because it also leads to deterrence in terms of cost.” (MSP). In addition, there can be overstrain through huge data amounts and stakeholders, such as physicians, may not have the time to analyze them. Relevance and quality of the data have to be assured, as well as there being intelligent algorithms which can aggregate the findings, otherwise there might be, according to one interviewee, “Paralyzing by analyzing” (MSP). In the context of treatment, almost all interviewees agreed that MSP always make the final decision and are responsible, so digital health innovation only supports but never replaces human intervention. It may be that “that's why we can't go there and only do medicine on the computer, because then that intuition will be lost [...]. We just have to empower, empowerment through intelligent data is also the future.” (MSP). But MSHT can replace some of the existing services that are provided by MSP, e.g. surgery aftercare at the patient's home using sensor-based devices. In this context new business models need to be developed which can also be seen as an opportunity. For example, “[...] to bring me a market advantage in certain patient segments.” (MSP). If there is high data transparency, there

are also new ways of control, for instance “I believe that the fact that the data will also become much more transparent will in turn have an effect on the medical service provision of the traditional players, because I may suddenly have to justify myself as an individual physician for something I have or have not done.” (SHI). Further, with respect to different interests regarding the degree of transparency, one interviewee believes that “[...] many actors are not interested in transparency, you have to say that. In the end, standardization leads to enormous transparency.” (I&I). The take away being that data openness is heavily tied to cost and time expenditure, as well as to an overstrain through large data amounts for MSP. As a result, adjustments of business models are necessary. To facilitate these changes, the right incentives in the context of data openness and transparency must be created.

Individual User Level. The user possesses health data sovereignty and controls data privacy. As we were told by one interviewee, “I [patient] have the data sovereignty. And also the possibility to provide my information to other players, because I decide whether I want to or not.” (SHI). There is often an emphasis on the voluntary participation of the user in donating data within the system “and then, we all have to get used to the fact that the patient decides to whom s/he gives the data.” (MSP). For this reason, only the collective action of many users donating their data can realize data openness on a collective ecosystem level (Constantinides and Barrett 2015) in order to improve disease prediction. Next to this, there is tension between value creation and value appropriation (Nambisan et al. 2019): If a user donates (sensitive) health data, the value is created via big data analyses and training of algorithms and the collective ecosystem appropriates value by improving treatment. From a societal perspective, donating data is a good thing, but there is no “direct and quantifiable” value appropriation for the user. Looking at the overall incentives, there must be added value for the user in data donation which exceeds privacy concerns. One interviewee explained that, “I am not a friend of the fact that the data is donated voluntarily [...]. And I would like a compensation or a kind of reimbursement model for the data producers.” (I&I). In summation, apart from an intrinsic motivation, a user’s incentive to donate data and enable data openness is rather low within the current ecosystem design.

Conclusion and Future Research

In summary, our qualitative study analyzed data from interviews with 30 healthcare stakeholders using a Grounded Theory approach. As part of a conceptual model we developed, we pinpointed a *health service improvement cycle* and how it works in the context of integrating mobile sensor-based health technologies into digital health ecosystems. This consists of data acquisition, flow, processing and interpretation for continuous service improvements and demonstrates the difficult process of developing sustainable business models within the German healthcare system. In this context, we also identified the importance of ecosystem design and governance strategy in the context of the “paradox of openness”, which includes stakeholder group-specific incentives and disincentives for data openness and data sharing on three levels. These are the individual user, the ecosystem-stakeholder-group, and the collective ecosystem level. Practically, our findings can inform the derivation of stakeholder-specific tactics and implementation strategies to overcome barriers for embedding MSHT into the healthcare system. For instance, they may help to better address the needs of medical service providers, health insurances, and patients via consideration of their specific requirements. This can also guide business model development for mobile health startups, as well as foster alignment of stakeholders and cross-group collaboration.

While the study is limited by the number and selection of stakeholders and stakeholder groups, this is generally in line with existing studies (Mantzana et al. 2007). We would also like to acknowledge that as a limitation, most interviews were conducted via telephone, posing a possible barrier to catching facial expressions and non-verbal cues. There might be potential bias caused by personal opinions and perceptions of interviewees (e.g. the voluntary participation in the interview study is most likely connected to some degree of digital affinity). The study is also limited by its focus on the German market and associated legal and regulatory conditions. For future research, including additional stakeholder groups, especially of patients and their incentive structures, can generate further insights and perspectives. This could enable the deriving of strategies for stakeholder alignment. Moreover, considering disease-specific requirements as well as the different types of sensor-based mobile health business models is promising. We also earmark for future research, those concepts for developing sustainable business models which are enabled by an ethical, socially impactful and regulatorily compliant health data cycle which from our perspective deserves special attention.

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